able to expect that a patient may experience some mild anxiety or stress from disorientation to their environment due to the opaque glasses and auditory stimulation masks normal sounds from their surroundings. It is expected that the presence of their caregiver and once the individual becomes more familiar with the treatment that this anxiety or stress will be reduced.

[1095] The study may involve unknown or unforeseen side effects or complications other than those mentioned above. If the above complications occur, they may lead to follow-up evaluation, monitoring, and care.

[1096] r. Minimization of Risk: The following measures will also be taken to minimize risk to participants as part of this investigational plan:

[1097] 1. Physicians and research staff will receive appropriate training prior to using the system. Training will include instruction on setup and treatment session management.

[1098] 2. Patients with history of or risk factors for seizure will be excluded from participation in the study.

[1099] 3. Instructions for Use are provided with each system.

[1100] 4. Patients will be closely monitored at regularly scheduled intervals for the duration of the study.

[1101] s. Summary: The detrimental effects of cognitive impairment are well established and a novel treatment approach is worthy of investigation. Non-invasive sensory stimulation may provide one such novel therapy. Although there are several theoretical risks that could be associated with the device and treatment, the likelihood and severity of those risks is believed to be low and will be carefully monitored in the study. The potential benefits could include symptomatic relief and slowed disease progression, which justify the investigation of non-invasive sensory stimulation in this study.

[1102] t. Sponsor Role and Responsibilities: The study sponsor's responsibilities include:

[1103] 1. Ensuring that the study is designed and managed in compliance with all appropriate regulatory standards and is conducted according to the study protocol.

[1104] 2. Selecting Investigators, qualified by training and experience, to conduct the study.

[1105] 3. Providing appropriate training to Investigators, site study staff, and all sponsor representatives.

[1106] 4. Providing the neural stimulation orchestration system only to participating Investigators and subjects, and tracking the shipment and disposition of all product.

[1107] 5. Monitoring study data at research sites, including confirmation that participant informed consent is obtained and on-going safety levels remain acceptable for the duration of the trial.

[1108] 6. Ensuring that prior to commencement of the study in each participating center, the sponsor has on file:

[1109] A. Written IRB approval

[1110] B. Approved study-specific participant informed consent

[1111] C. Signed Investigator's Agreement

[1112] D. Investigators' current curriculum vitae

[1113] E. Identified and coordination with local representative

[1114] Amendments: The CIP, Investigator Brochure, case report forms, informed consent form and other subject information, or other clinical investigation documents shall be amended as needed throughout the clinical investigation, and a justification statement shall be included with each amended section of a document. Proposed amendments to the CIP shall be agreed upon between the sponsor and principal investigator, or the coordinating investigator. The amendments to the CIP and the subject's informed consent form shall be notified to, or approved by, the IRB. The version number and date of the amendments shall be documented.

[1115] u. Statistical Analysis Plan Summary: This is a multi-center, prospective, non-randomized, controlled study designed to evaluate the safety and clinical utility of sensory stimulation in the treatment of Alzheimer's disease. The primary effectiveness endpoint of this trial is the change in ADAS-Cog from baseline to 6 months. The primary safety endpoint is the incidence and nature of Adverse Events (AE).

[1116] Repeated objective measures such as data classified from actigraphy recordings may allow for sufficient statistical power to discern effects between the treatment and control groups. The variance of the psychometric scales have been demonstrated longitudinally on health control populations, mild cognitive impairment, and more advanced Alzheimer's patients through projects such as the Alzheimer's Disease Neuroimaging Initiative. A substantial treatment effect from the sensory stimulation would be required to demonstrate a difference between the treatment and control groups in the design of this study. Therefore, descriptive statistics will be used to evaluate the primary and secondary endpoints, and ad-hoc secondary analyses will be performed to inform the subsequent design of clinical studies based on this feasibility data.

1-26. (canceled)

27. A system comprising:

a) a stimulus-emitting component capable of providing a neural, an auditory, or a visual stimulus to a subject;

b) a processor;

c) a memory device; and

d) a feedback sensor,

wherein said processor receives an indication of a physiological, cognitive, neural, and/or physical assessment of the subject through said feedback sensor and, instructs said stimulus-emitting component based on the indication to adjust at least one parameter associated with said neural, auditory, or visual stimulus to create a therapeutic improvement in the degree of neural entrainment exhibited by neurons in at least one brain region of the subject.

28. The system of claim **27**, wherein said physical assessment of said subject involves ascertaining at least one of said subject's: compliance with proper use and positioning of said system, eye status, alert or sleep status, or environment and surroundings.

29. The system of claim **27**, wherein said neural assessment of the subject is received using brain wave sensors, an electroencephalography (EEG) device, an electrooculography (EOG) devices, or a magnetoencephalography (MEG) device.

30. The system of claim **27**, wherein said cognitive assessment of said subject is obtained through questions